K 032133

JUL 2 1 2003

M 510(k) Summary

[As Required by 21 CFR 807.92]

Broda Enterprises Incorporated's
Model 587 Manual Wheelchair

Submitted by:	Broda Enterprises Incorporated 385 Phillip Street Waterloo, Ontario, Canada N2L 5R8 Phone: (519) 746-8080 Fax: (519) 746-8616
Contact Person:	Phillip McTaggart Controller, Regulatory Affairs
Date Prepared:	May 8, 2003
Sponsor:	Broda Enterprises Inc. 385 Phillip St Waterloo, Ontario, Canada N2L 5R8 Phone: (519) 746-8080 Fax: (519) 746-8616
Proprietary Name:	Broda Model 587 Manual Wheelchair
Common Name:	Wheelchair
Classification Name:	Wheelchair, Manual Class 1 (21 CFR 890.3850)
Predicate Device:	Invacare Corporation Model Tracer Series Manual Wheelchair (K935398: March 1, 1994)
Intended Use:	The intended use of the Broda Model 587 Manual Wheelchair is to provide mobility to persons that may be limited to a sitting position.

Technological Characteristics and Substantial Equivalence

Device Description: The Model 587 Broda Manual Wheelchair is a manually operated, user propelled mechanical wheelchair. The intended use is to provide mobility to persons that may be limited to a sitting position. The product consists primarily of a rigid steel frame, large rear wheels with hand rims for propelling the chair, and smaller front pivoting casters for steering and turning. This is a non-folding rigid type of wheelchair which can be customized for use by patients that weigh up to 250 lbs.

Seat width ranges from a minimum of 14" wide to a maximum of 20" wide in two inch increments, with the 16" and 18" widths offered as standard. Seat depths range from a minimum of 15.5" deep to a maximum of 20" deep in 1.5" increments, with the 17" depth offered as standard. Seat to floor dimensions range from 15" high to 20" high in 1" increments, with the 19" height offered as standard. Back height ranges from a minimum of 24" high to a maximum of 32" high in 2" increments, with the 24" height offered as standard.

The rigid frame is constructed of round, steel tubing that is MIG welded. The tubing is 1" outside diameter (O.D.) with a wall thickness of 0.065". A rigid, non-folding frame is not used on the predicate device and does not affect the safety and effectiveness of the chair.

The Broda Model 587 Wheelchair offers up to 22 degrees of seat tilt with infinite positioning. The seat tilt controls slumping and sliding, reduces the reliance on restraints, and increases the general comfort level for the occupant. This specification is not available on the predicate devices and does not affect the safety and effectiveness of the chair.

The seat and back are strapped with vinyl strapping that is riveted to the steel tube. The strap is 0.128" thick and 1.5" wide. The strapping is used to better distribute the weight of the occupant, hence reduce the contact pressures on the occupant, which provides added comfort. The strapping also controls heat and moisture buildup and can prevent skin breakdown. The strapping is further covered with a woven polyester/spandex material called Triptex. The strapping is not used on the predicate device and does not affect the safety and effectiveness of the chair.

Substantial Equivalence: The Broda Model 587 Manual Wheelchair is substantially equivalent to the Invacare Tracer Manual Wheelchair (K935398).

Performance Data

The Broda Model 587 Manual Wheelchair has been tested using the testing methods specified in the Rehabilitation Society of North America (RESNA) Standard ANSI/RESNA WC/Vol. 1-1998 "Requirements and Test Methods for Wheelchairs (Including Scooters)". Results demonstrate that the product meets its' specification. Additionally, the Triptex upholstery meets CAL 117 Standard for flame retardation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Broda Enterprises, Incorporated
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462

Re: K032133
Trade/Device Name: Broda Model 587 Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: II
Product Code: IOR
Dated: July 10, 2003
Received: July 11, 2003

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B Statement of Indications for Use

Applicant:	Broda Enterprises Incorporated
510(k) Number (if known):	TBD
Device Name:	Broda Model 587 Manual Wheelchair
Indications For Use:	The intended use of the Broda Model 587 Manual Wheelchair is to provide mobility to persons that may be limited to a sitting position.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032133

(Optional Format 1-2-96)